



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10531 and CMS-R-43]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-10531 Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD)

CMS-R-43 Conditions of Coverage for Portable X-ray Suppliers and Supporting Regulations

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD); Use: The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, "Transcatheter Mitral Valve Repair (TMVR)". The TMVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all-cause mortality and quality of life. In order to remove the data collection requirement under this coverage with evidence development (CED) NCD or make any other changes to the existing policy, we must formally reopen and reconsider the policy. We are continuing to review and analyze the data collected since this NCD was effective in 2014

We find that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TMVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TMVR technologies for the treatment of mitral regurgitation (MR).

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TMVR is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under section 1862(a)(1)(A) of the Act. The data will also include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ-10) to assess health status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0-100, in which higher scores reflect better health status.

The conduct of the STS/ACC TVT Registry and the KCCQ-10 is pursuant to Section 1142 of the Social Security Act (the ACT) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries. Form Number: CMS-10531 (OMB control number: 0938-1274); Frequency: Annually; Affected Public: Private sector (Business or other for-profits); Number of Respondents:

3,897; Total Annual Responses: 15,588; Total Annual Hours: 5,456. (For policy questions regarding this collection contact Sarah Fulton at 410-786-2749.)

2. Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title of Information Collection: Conditions of Coverage for Portable X-ray Suppliers and Supporting Regulations; Use: The requirements contained in this information collection request are classified as conditions of participation or conditions for coverage. Portable X-rays are basic radiology studies (predominately chest and extremity X-rays) performed on patients in skilled nursing facilities, residents of long-term care facilities and homebound patients. The CoPs are based on criteria described in the law, and are designed to ensure that each portable X-ray supplier has properly trained staff and provides the appropriate type and level of care for patients. We use these conditions to certify suppliers of portable X-ray services wishing to participate in the Medicare program. This is standard medical practice and is necessary in order to help to ensure the well-being, safety and quality professional medical treatment accountability for each patient. There is a significant increase in the burden due to burden that was not accounted for in the previous information collection request. Form Number: CMS-R-43 (OMB Control number: 0938-0338); Frequency: Yearly; Affected Public: Business or other for-profit and Not-for-profit institutions; Number of Respondents: 5,986,509; Total Annual Responses: 5,987,018; Total Annual Hours: 532,959. (For policy questions regarding this collections contact Sonia Swancy at 410-786-8445.)

Dated: April 4, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

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